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10/802,166

03/17/2004

James Robert Schwartz

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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1613

MAIL DATE

DELIVERY MODE

12/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/802,166 | Applicant(s) SCHWARTZ ET AL. | |
| | Examiner ERNST V. ARNOLD | Art Unit 1613 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-13,18-25 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7-13, 18-25 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2, 4-6, 14-17 and 26 have been cancelled. Claims 1, 3, 7-13, 18-25 and 27 are pending. Applicant's amendment has necessitated a new ground of rejection. Accordingly, this Action is FINAL.

Terminal Disclaimer

The terminal disclaimer filed on 9/30/10 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 7026308 has been reviewed and is accepted on 10/29/10. The terminal disclaimer has been recorded. The terminal disclaimer filed on 2/6/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 10/803126 has been reviewed and is accepted on 3/12/09. The terminal disclaimer has been recorded.

Withdrawn rejections:

Applicant's amendments and arguments filed 9/30/10 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

Art Unit: 1613

obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 7-13, 18-25 and 27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gavin et al. (WO 01/00151) and Bhat et al. (WO 96/25913).

Applicant claims:

(currently amended) A composition comprising:

- a) from ~~about 0.001% to about 5 %~~ of a zinc-containing layered material ~~selected from the group consisting of wherein the zinc-containing layered material is an impurity containing basic zinc carbonate, zinc carbonate hydroxide, hydrozincite, zinc-copper carbonate hydroxide, aurichalcite, copper-zinc carbonate hydroxide, rosasite, phyllosilicate containing zinc ions, layered double hydroxide, hydroxy double salts and mixtures thereof;~~
- b) from about 10 % to about 50% of a surfactant including a surfactant with an anionic functional group;
- c) from about 0.01% to about 5% of a pyrithione or a polyvalent metal salt of a pyrithione;

~~rein the zinc-containing layered material impurity containing basic zinc carbonate has a relative zinc lability of greater than about 15% and further wherein the ratio of surfactant to zinc-containing layered material- impurity containing basic zinc carbonate is greater than or equal to 2 to 1.~~

Determination of the scope and content of the prior art

(MPEP 2141.01)

Gavin et al. teach a topical anti-dandruff composition for treating microbes comprising:

- From 0.001% to 10% zinc pyrithione or polyvalent metal salts of pyrithione;
- from 0.001 to about 10% of a metal ion source such as zinc salt or copper salt or mixtures thereof; and
- an anionic deterative surfactant (about 5 to about 50% by weight) for a topical carrier (Page 8, lines 10-15 and Claim 1).

Less than 50% of the polyvalent metal salt dissociates into free pyrithione in the composition (claim 2). The ratio of surfactant to zinc containing layered material can be greater

Art Unit: 1613

than or equal to 2 to 1 by simple manipulation of the amounts taught above. The pH of the compositions ranges from about 2 to about 10 and most preferably from about 5.5 to about 7.5 thus within the scope of instant claims 9-11 (Page 7, lines 7-9). The addition of cationic deposition polymers (instant claim 18) is taught (Page 20, lines 30-34-page 25, line 30). The addition of conditioning agents (instant claim 19) is taught (Page 35, line 12- page 47, line 16). Suspending or thickening agents are anticipated and crystalline suspending agents are preferred thus reading on instant claims 20-22 (Page 18, line 27-page 20, line 28) Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence reading on the method of instant claims 23-25 (Claim 9). Gavin et al. teaches applying the composition and then rinsing off with water (page 50, lines 12-17).

Bhat et al. teach personal care product compositions comprising a surfactant and the zinc salt monophasic zinc hydroxycarbonate in an amount of 0.1-20 % by weight (Claims 1 and 2). The structure of the zinc compound is $Zn_5(OH)_6(CO_3)_2 \cdot X H_2O$ where X varies between 0 and 4 (Page 6, lines 23-27). When X=0 then the same formula for basic zinc carbonate as disclosed by Applicant is taught (see instant specification page 6, line 6). It is the Examiner's position that the basic zinc carbonate taught by Bhat et al. would have the same level of zinc lability as instantly claimed (claims 1, 12 and 13) in the absence of evidence to the contrary. Indeed, Bhat et al. teach release of zinc ions from zinc hydroxycarbonate (page 7, lines 31-35). **Bhat et al. teach synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos** (page 8, lines 1-4). Bhat et al. teach the surfactant can be sodium lauryl sulphate, an anionic surfactant, in the amount of 2.5% (Page 12, line 10).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Gavin et al. do not expressly teach a composition comprising as the zinc containing layered material is an impurity containing basic zinc carbonate that has a zinc lability of greater than 15%, 20% or 25%. This deficiency in Gavin et al. is cured by the teachings of Bhat et al.

2. Gavin et al. do not expressly teach a method comprising wetting the hair or skin first with water and then applying the composition.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Gavin et al. comprising as the zinc containing layered material an impurity containing basic zinc carbonate that has a zinc lability of greater than 15%, 20% or 25%, as suggested by Bhat et al., to the composition of Gavin et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest adding zinc salts to the composition but not specifically basic zinc carbonate and Bhat et al. cure this deficiency by teaching the synergistic action of zinc hydroxycarbonate with antidandruff actives like zinc pyrithione in shampoos. One of ordinary skill in the art would desire the synergistic action of the zinc hydroxycarbonate with the anti-dandruff active zinc

Art Unit: 1613

pyrithione in the composition to produce the best results. The “impurity containing basic zinc carbonate” is intrinsic in the composition of Bhat et al. because all that is required that some element/component of infinitesimally small amount be present since the instant claims do not define the ‘impurity’ or the amount of the ‘impurity’ present. Hence, a single atom would represent an ‘impurity’ but not be within means of detection. The ‘zinc lability’ is an intrinsic property of the zinc salts since they are the same as instantly claimed. With regards to the other zinc and copper salts, it is merely judicious selection of zinc and copper salts by one of ordinary skill in the art in the absence of evidence to the contrary. One of ordinary skill in the art would have had a reasonable expectation of success because it appears that any zinc or copper or mixed zinc-copper salt will work in this invention.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Gavin et al. by wetting the hair or skin first and then applying the composition and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it reads on stepping into a shower with the water running and getting wet, applying the composition and then rinsing it off. It is well within the skill of the ordinary artisan to take a shower and not inventive skill is required to get wet first before applying the composition in the absence of evidence to the contrary.

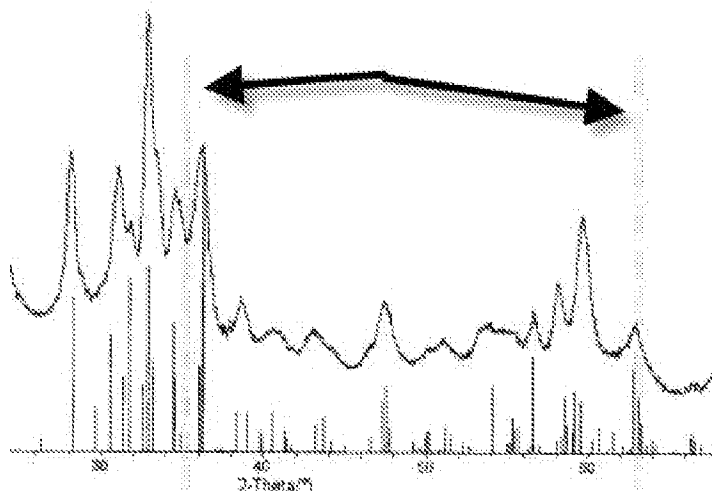
A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (In re Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

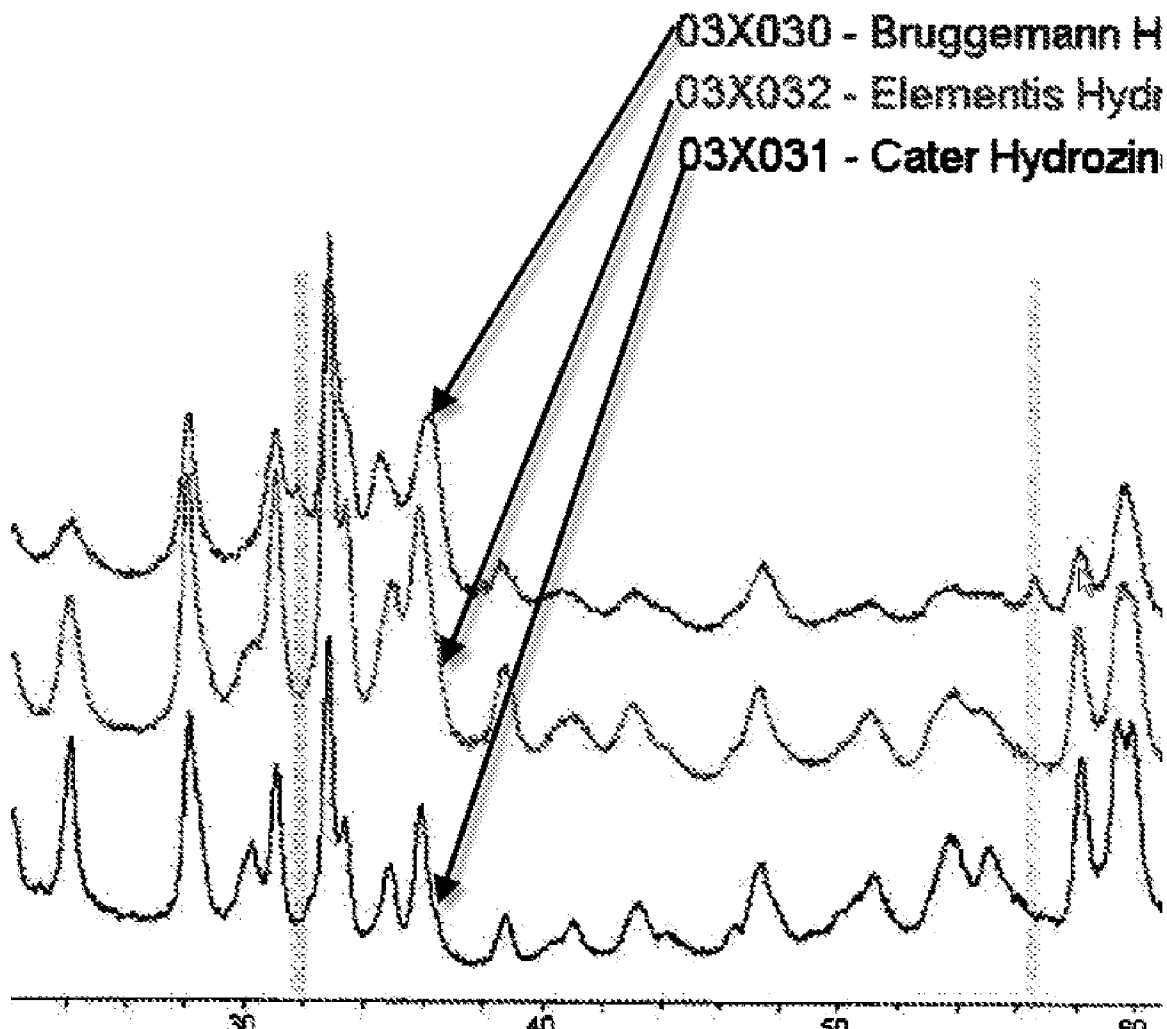
Response to arguments:

Applicant has provided a Declaration under 37 CFR 1.132 for the Examiner's consideration. The Declaration states that Bhat et al. makes 'monophasic' zinc hydroxycarbonate which means 'without any other impurity phases...present...'. The Declaration also states that 'monophasic' means that only a single material is identifiable by its X-ray diffraction pattern in the field of x-ray diffraction of crystal structures. Note that Applicant does not say powder diffraction. A X-ray diffraction (XRD) pattern of hydrozincite is provided in Table 1 and additional peaks are highlighted in yellow, which does not work well in a gray scale, to indicate differences with basic zinc carbonate of the instant invention.



See above where the Examiner has inserted arrows to what is believed to be the 'yellow highlights' that indicate additional peak beyond those that represent pure basic zinc carbonate. Clearly there is no peak at about 35 2-theta but there is an indication on the axis for a peak and there is a peak at about 63 2-theta but that would be expected because the pattern has a peak at that position. Additionally, this pattern is more in alignment with a powder XRD pattern than a crystal structure and there is nothing of record to show that powder XRD can discriminate between phases. XRD of crystals and XRD of powders are two different techniques. Also, there are 3 substances listed in the top right of the Table which adds to the confusion as to what is really being observed in the Table; hydrozincite, zinc oxide or Bruggemann hydrozincite.

Table 2 compares different samples of basic zinc carbonate and some appear primarily monophasic while others do not. In Table 2, Applicant asserts that the Bruggemann sample is multi-phasic and the samples from Cater and Elementis show less evidence of multi-phasic. Since the scan is in color the Examiner will assume that the top scan relates to the Bruggemann sample, the middle to the Elementis sample and the bottom to the Cater sample. See below:



The Declaration states that higher purity materials have lower relative zinc lability. In Table 3, the closest sample to 'monophasic' is the Cater sample which has a relative zinc lability of 42.3%.

After careful consideration of the Declaration data, the Examiner can only conclude that the most 'monophasic' basic zinc carbonate of the highest purity tested by Applicant still has a relative zinc lability of 42.3% which is greater than the instantly claimed amounts. Bhat et al. used the same powder XRD technique to determine the crystalline nature of the product (page 9,

Art Unit: 1613

lines 21-23). Therefore the Declaration is not persuasive to overcome the rejection because even the highest purity and thus lowest zinc lability material shown by Applicant, which would be analogous to the material used by Bhat et al., is still within the instantly claimed amount of zinc lability. The rejection is maintained.

Applicants arguments are addressed to the Declaration data and, respectfully, these arguments are not persuasive as explained above. Applicant argues crystallite size but this is not a limitation in the claims. See MPEP 2145: VI. ARGUING LIMITATIONS WHICH ARE NOT CLAIMED “Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.” In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057. The fact remains that the most monophasic material tested by Applicant still meets the instant claim limitations of zinc lability.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Response to arguments:

1. Claims 1, 3, 7-13, 18-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-12, 16-32, and 34-39 of copending Application No. 11/602770. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions, shampoo and methods of treating dandruff with an effective amount of a particulate zinc material (such as basic zinc carbonate); 0.01-5% zinc pyrithione, 1-50% anionic surfactants. The copending application discloses cationic deposition polymers, conditioning agents, suspending agents, pH ranges, relative zinc labilities and various surfactants.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant requests that this rejection be held in abeyance until allowable subject matter is indicated. Until that time the rejection is maintained.

2. Claims 1, 3, 7-13, 18-22 and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 13-30, 35 and 37-40 of copending Application No. 11/890684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff comprising a particulate zinc material (basic zinc carbonate as well as every other zinc layered material instantly claimed (see claims 25 and 26)); 0.01 to about 5% zinc pyrithione; 1% to about 50% anionic surfactant; pH; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach the amount of zinc layered material or a ratio of surfactant to zinc layered material of greater than or equal to 2:1 or impurity containing basic zinc carbonate.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result. Furthermore, the disclosure of the genus of basic zinc carbonate includes all forms of basic zinc carbonate including those with impurities.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant asserts that claim 1 as amended is the same as claim 26 which was not rejected. This is not found to be persuasive as the copending has the same materials and the same zinc lability and upon further consideration the rejection is maintained. While the copending may not teach an impurity containing basic zinc carbonate, the disclosure of basic zinc carbonate embraces all forms of basic zinc carbonate including those with impurities. The comprising language allows for additional components. Applicant's arguments are not persuasive.

3. Claims 1, 3, 7-13, and 18-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 11-27 and 33-46 of copending Application No. 11/899106. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant subject matter embraces or are embraced by the subject matter of the copending application. The copending application discloses compositions and methods for treating dandruff, fungal and microbial infections comprising a 0.001% to about 10% zinc containing material (basic zinc carbonate); 0.01 to about 5% zinc pyrithione; 5% to about 50% anionic surfactant; pH is greater than about 7; relative zinc lability; cationic polymer; conditioning agent; and suspending agent.

The copending application does not expressly teach a ratio of surfactant to zinc layered material of greater than or equal to 2:1 or impurity containing basic zinc carbonate.

However, these are result effective variables and one of ordinary skill in the art would optimize the amount of each ingredient to arrive at the desired result. Furthermore, the disclosure of the genus of basic zinc carbonate includes all forms of basic zinc carbonate including those with impurities.

Therefore, the Examiner concludes that one of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending application.

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Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

Art Unit: 1613

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST V. ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613